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(54) BULB CATHETER

(71) We, LUBOMIR HANECKA, of 1050 Vienna, Siebenbrunnengasse 88, Austria, and FRIEDRICH OLBERT, of 1160 Vienna, Gallitzinstrasse 108, Austria, both Austrian citizens, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to a bulb catheter comprising two tubes, one slidable inside the other, and a tubular bulb disposed around the inner tube and adapted to be pressurised with a liquid or gaseous medium.

Bulb catheters of this kind serve as dilators for blood vessels the internal volume of which is substantially or entirely occluded due to atherosclorosis. Atherosclorosis is a combination of changes in the interior of arteries and a focal accumulation of lipides, complex carbohydrates, blood and blood products, fibrous tissue and calcium deposits. Such deposits form partial occlusions (so-called stenoses) or total occlusions in the arteries.

Arteries which have been occluded by such deposits can be opened again by means of bulb catheters of the kind described above if such a catheter is introduced into the artery so that its bulb is situated in the region of the stenosis and is then pressurised with an appropriate pressure so that the mass forming the stenosis can be pressed apart and can distribute itself along the longitudinal extent of the artery; a process which is accompanied by a specific consolidation of the mass which has thus been prised apart.

In a known bulb catheter of the kind described above the bulb is formed by a portion of the outer tube which has been enlarged by expansion, the said outer tube being manufactured from plastics, for example polyvinylchloride. The outer tube is slid with relatively slight clearance over the inner tube, since the latter must provide the outer tube with the stiffness required for the insertion or advancement along the artery. The known bulb catheter suffers from the disadvantage that evacuation of the bulb—a procedure which has been found necessary for the insertion or removal of the bulb catheter into or from the artery—causes the bulb sleeve to form folds about the inner tube, that is to say longitudinal folds as well as folds in the circumferential direction. Accordingly, sliding the bulb through the puncture place (for example that Arteria Femoralis immediately below the inguinal band) causes the bulb sleeve to gather or to increase its circumference in this region so that the insertion of such a bulb catheter into or the removal from an artery is substantially obstructed. This results in an increase in size of the puncture aperture in the vessel itself. Also the manipulation of such catheters does not eliminate the risk of local thrombosis.

According to the invention there is provided a bulb catheter which comprises two tubes, one slidable axially inside the other, and a tubular bulb disposed around the inner tube and adapted to be pressurised with a liquid or gaseous medium and whose internal space communicates with the space between the outer tube and the inner tube, the bulb being sealingly attached at one end to the inner tube and sealingly attached at the other end to the outer tube, so as to seal the space between the outer tube and the inner tube against the surrounding medium, the two tubes being pressure-resistant; the tubular bulb exhibiting in its non-inflated state a smooth unwrinkled tubular external form for facilitating passage of the catheter along a blood vessel, the tubular nature of the bulb being maintained on inflation.

Accordingly, continued insertion of the inner tube, while the outer tube remains stationary, enables the bulb to be stretched in the longitudinal direction so as to achieve a reduction of the circumference of the said bulb and to prevent gathering together of the bulb material when it is slid through the puncture aperture. It is also possible, without having to dismantle the entire bulb

BALLOON CATH

catheter, to exchange bulbs which have become defective by incorrect handling.

The bulb catheter according to the invention therefore offers the following advantages:

1. Only a small incision or a relatively small puncture place is needed in the region of the arterial wall.
2. The catheter has a relatively small internal volume and so can be guided relatively easily even through stenoses of substantial size.
3. The risk of embolism due to detachment of plaque in the region of the internal volume of the vessel is reduced with the bulb catheter according to the invention, because the atherosclerosis material is not pushed away but by inflation of the bulb is displaced uniformly towards the wall of the vessel and is compressed.
4. It is possible to control the extent of catheter extension by controlling both the pressure and the degree of relative extension of the tubes.

It is also possible to use the same catheter for dilating constrictions in other hollow organs, for example in the region of the oesophagus (cardia), in the pylorospasmus or in the region of the ductus choledochus.

To prevent an irregular and unlimited extension of the bulb in dependence on the external resistance, the bulb, which can be stretched by relative displacement of the tubes as they are pushed one inside the other, can be reinforced by means of a fabric, more particularly a synthetic fibre fabric. This also ensures that in the pressurised state the bulb has approximately the same diameter over its entire length, and that portions not situated in the regions subject to stenosis the bulb sleeve is not expanded to an extent greater than at the place at which the internal volume of the blocked artery is to be expanded. To this end the filaments of the reinforcement fabric preferably extend along helices of opposite sense so that only a limited extension of the bulb sleeve in the radial direction is allowed, whilst at the same time permitting axial stretching. This feature also ensures that sfretching of the bulb may reduce the external diameter thereof below that of the external tube. When pressurised the bulb shortens in accordance with the increase of diameter but this is limited by the reinforcement fabric.

Advantageously the tubes, which are inserted one within the other, can be fixed in different relative positions by an arresting device so that manipulation of the catheter is substantially simplified during operation.

Furthermore, the bulb catheter can communicate by means of a T-piece with a pressure gauge or automatic valve so that the pressure conditions in the bulb can be monitored and regulated during operation.

Finally, for special applications of the bulb catheter the point and/or the frontal portion thereof can be curved so that it can be selectively introduced into a lateral artery, for example a renal artery.

An embodiment of the invention is illustrated in the accompanying drawing wherein:

Figure 1 shows a general view of an assembly comprising a bulb catheter according to the invention, the bulb being shown in the pressurised state;

Figure 1*a* shows the bulb to the same scale but in the stretched state;

Figure 2 shows to an enlarged scale the bulb region of the catheter with the pressurised bulb in longitudinal cross-section; and

Figure 3 shows, also to an enlarged scale and in longitudinal section, the proximal end of the catheter.

The part 1 of the bulb catheter which is to be introduced into the artery is provided at its distal end with a tubular bulb 2 and comprises two tubes, namely an outer tube 3 and an inner tube 4 which can be slid one inside the other. The bulb 2 is attached and sealed to the inner tube 4 by means of its end 2′ which is the leading end in the insertion direction, and is attached and sealed to the outer tube 3 by means of its end 2″ which is the trailing end in the insertion direction. The bulb 2 is disposed around the inner tube 4, the front end of which in the insertion direction is open, and the inner space 5 of the bulb 2 communicates with the space 6 between the inner tube 4 and the outer tube 3. The space 6 is thus sealed by the bulb 2 with respect to the surrounding medium. The bulb 2 can thus be pressurised via the outer tube 3 with pressure fluid which may advantageously be X-ray opaque. The numeral 7 refers to reinforcing fabric in the material of the bulb wall. The filaments of the reinforcing fabric 7 are embedded in the bulb material and extend in a helical configuration around the bulb, some of the helical filaments extending in a clockwise sense and the others in an anticlockwise sense.

The two tubes 3, 4 are formed of a pressure-resistant material and can slide axially relative to each other. This enables the bulb 2 to be stretched in the axial direction (see Fig. 1*a*). In the course of such stretching the length of the bulb 2 increases by approximately 60% and the diameter thereof simultaneously decreases to approximately 40% of the dimension of the pressurised bulb.

As shown in Figure 3, at the proximal end of the bulb catheter the end of the outer tube 3 is secured in a sealed manner to a T-connector 8; which comprises a clamping device 9 for the end of the outer tube 3, a lateral connecting socket 10 which communicates with the space 6 and a bushing for the inner tube 4. The bushing is sealed with respect to the exterior by means of an O-ring 11 and extends axially around the inner tube 4. At its proximal end the inner tube 4 is provided with a connector 12 for hypodermic syringes or the like so that heparine, physiological saline solution, X-ray opaque media or the like can be introduced into the artery via the inner tube 4 during operation. The numeral 13 refers to a locking device by means of which the two tubes 3, 4 can be fixed relative to each other when the bulb 2 is in the stretched state (Fig. 1*a*). The locking device 13 comprises a resilient lever 14 whose end, in the insertion direction, is provided with a ratchet extension 15 and a sloping ramp surface 16. A circumferential groove 17 is provided in the T-connector 8 into which the ratchet extension 15 engages when the bulb 2 is stretched.

A syringe 18 which is connected via a delivery duct 19 to the lateral connecting socket 10 of the T-connector 8 is provided for pressurising the bulb 2. A pressure gauge 20 for pressure monitoring is connected to the delivery duct 19 via a T-piece 21.

If stenosis or arterial occlusion is to be removed a guide wire is first introduced into the artery after puncturing the vessel with a horizontal cannula needle, the end of the wire being carefully pushed through the stenosis or the occlusion. When the guide wire is in position the bulb catheter with the tubes 3 and 4 fixed relative to each other and the bulb in the stretched state is advanced by introducing the wire into the inner tube 4 through the puncture duct. The catheter is moved along the guide wire into the artery or its end is moved into the stenosis region until the bulb is situated in the region of the narrowest point of the artery. The relative interlocking of the two tubes 3, 4 is then released and the bulb 2 is pressurised with fluid by means of the syringe 18. The bulb will then expand in the radial direction to the desired dimension while its length becomes shortened, so that, as already mentioned initially, the artery is recanalized. In the case of stenoses which are longer than the bulb, the catheter is inserted further and the expansion is repeated once or several times. The bulb 2 is then slightly evacuated by means of the syringe 18 and subsequently, accompanied by further evacuation and insertion of the inner tube 4 further into the artery, is brought into the stretched state. Then both tubes are locked against each other in this position. The catheter in its stretched state is then removed from the artery.

To facilitate manipulation and to ensure the correct manipulation procedure of the catheter it is advantageous to couple the proximal end of the inner tube 4 to the syringe 18, for example by mechanical means, so that prior to stretching of the bulb the latter is first automatically evacuated so as to prevent any overstressing of the inner tube and of the bulb material.

Within the scope of the invention the end and/or the front portion of the bulb catheter can be curved so that it can be selectively introduced into a lateral artery, for example a renal artery.

WHAT WE CLAIM IS:—

1. A bulb catheter which comprises two tubes, one slidable axially inside the other, and a tubular bulb disposed around the inner tube and adapted to be pressurised with a liquid or gaseous medium and whose internal space communicates with the space between the outer tube and the inner tube, the bulb being sealingly attached at one end to the inner tube and sealingly attached at the other end of the outer tube, so as to seal the space between the outer tube and the inner tube against the surrounding medium, the two tubes being pressure-resistant; the tubular bulb exhibiting in its non-inflated state a smooth unwrinkled tubular external form for facilitating passage of the catheter along a blood vessel, the tubular nature of the bulb being maintained on inflation.

2. A bulb catheter according to Claim 1, wherein the bulb can be stretched by relative sliding of the tubes one inside the other, and is reinforced by means of a fabric.

3. A bulb catheter according to Claim 2, wherein the fabric is composed of synthetic fibres.

4. A bulb catheter according to Claim 2 or 3, wherein filaments of the reinforcement fabric extend along helices of opposite senses.

5. A bulb catheter according to any preceding claim, wherein the tubes can be fixed in different relative positions by means of a locking device.

6. A bulb catheter according to any preceding claim, wherein the front portion thereof is curved so that it can be selectively introduced into a lateral artery.

7. A bulb catheter substantially as herein described with reference to and as shown in the accompanying drawings.

8. An assembly which comprises a catheter according to any preceding claim, a T-piece communicating with the space

between the outer tube and the inner tube, and a pressure gauge connected to the T-piece.

9. An assembly which comprises a catheter according to any one of claims 1 to 7, a T-piece communicating with the space between the outer tube and the inner tube, and an automatic valve connected to the T-piece for regulating the pressure of the pressurising fluid.

10. An assembly which comprises a bulb catheter, substantially as herein described with reference to and as shown in the Fig. 1 of the accompanying drawings.

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1566674 COMPLETE SPECIFICATION

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Sheet 1

FIG. 1

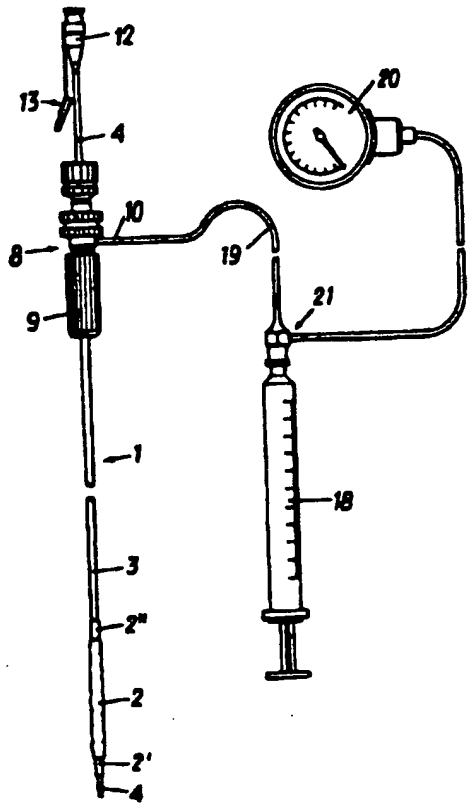

FIG. 1a

1566674 COMPLETE SPECIFICATION

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Sheet 2

FIG.2

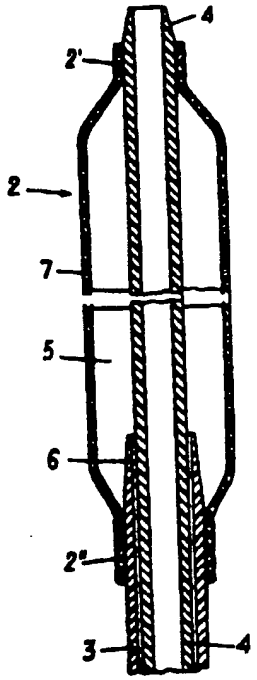
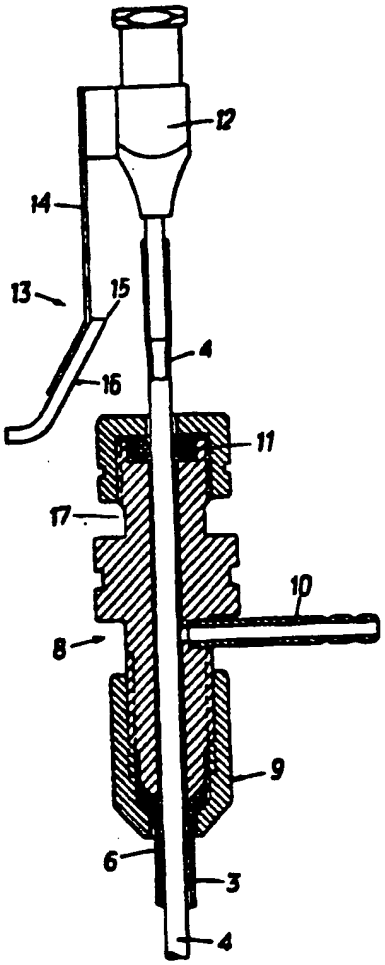


FIG.3



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SPECIFICATION NO.1566674

The following amendments were allowed under Section 29 on 20 September 1988

Page 1

Line 73 *After* two *insert* pressure resistant
Line 75 *After* bulb *insert* , reinforced by means of a fabric,
Delete line 85 *insert* medium, the arrangement being such that the bulb can be stretched by relative sliding of the tubes one inside the other,
Line 86 *Delete* resistant

Page 2

Line 37 *Delete* can be *insert* is

Page 3

Line 86 *After* two *insert* pressure resistant
Line 88 *After* bulb *insert* , reinforced by means of a fabric,
Delete line 98 *insert* medium, the arrangement being such that the bulb can be stretched by relative sliding of the tubes one inside the other,
Line 99 *Delete* sistant
Delete lines 105 to 109
For Claims 3 to 8 *read* 2 to 7
Line 111 *Delete* 2 *insert* 1 *delete* fabric *insert* reinforcement
Line 113 *After* Claim *insert* 1 or
Line 114 *Delete* or 3
Line 115 *Delete* fabric

Page 4

For Claims 9 and 10 *read* 8 and 9
Line 6 *Delete* 7 *insert* 6

The Patent Office 24 October 1988